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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/467317	Applicant( ) NOELLE [redacted]
	Examiner GAMBEL	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____.

2a)☐ This action is FINAL. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) ____ is/are pending in the application. 42-58

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☑ Claim(s) ____ is/are rejected. 42-58

7)☐ Claim(s) ____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☑ objected to by the Examiner. SEE OFFICE ACTION.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☑ Other: NOTICE TO COMPLY WITH SEQUENCE RULES

DETAILED ACTION

1. Claims 42-58 are pending.

Claims 1-41 have been canceled previously.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence.

See Figure 8.

Applicant is reminded to amend the specification (e.g. Brief Description of the Drawings) accordingly.

The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable from of the Sequence Listing in this rule 60 continuation. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents.

5. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-Reference to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Applicant is invited to consider deleting the Table of Contents on pages I-iii of the instant specification. Applicant is reminded that page numbering of the specification should start with page 1, not page I.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. New Matter:

Claims 42, 43, 48, 49 and 54-58 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:

"A method for inhibiting a humoral immune response .... " (claims 42, 43, 48, 49 and 54-58);

"A method for inhibiting ... to a protein specifically recognized by monoclonal antibody 5c8 produced by the hybridoma having ATCC No. HB 11048" (claims 48).

Applicant's amendment, filed 12/20/99 (Paper No. 3), directs written support of the newly claims to pages 17-19, pages 28-31 and certain original claims for "humoral immunity" and "5c8".

While the instant specification as filed, including the Uses of CD40CR on pages 19-21 in addition to the cited sections by applicant support methods of inhibiting B cell activation and immunoglobulin production, there appears insufficient written description in the specification as filed for "methods for inhibiting humoral immunity" and for methods employing the "monoclonal antibody 5c8".

The Illustrated Dictionary of Immunology (Cruse and Lewis, CRC Press, Boca Raton, 1995) discloses that humoral immunity is attributable to specific immunoglobulin antibody, which can result in both beneficial and deleterious reactions and is not clearly distinguished from cellular or T cell immunity (see page 143). Humoral immunity can comprise various cell types and mediators associated with the immune response. Humoral immunity is not limited to B cell activation and immunoglobulin production, as disclosed by the specification as filed.

It appears that the recitation of "5c8" may be a typographical error, given that claim 48 recites "the hybridoma having ATCC No. HB 11048" which produces the "MR1" antibody and does not produce the "5c8" antibody.

Applicant should amend the claim(s) accordingly.

If this is not the case, then the specification as filed does not provide written support for "5c8"

The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

9. This is a rejection under 35 USC § 112, first paragraph, "written description" (and not new matter).

Claims 43, 47, 49, 51, 53-58 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

There is insufficient written description encompassing "CD40CR" because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of "CD40CR" are not set forth in the specification as filed, commensurate in scope with the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.
Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant is relying upon certain biological activities and the disclosure of the limited representative species of a mouse CD40CR (e.g. see Sections 6.2.3 and 6.2.4 as well as Figures 4- 6) to support an entire genus of CD40CR as it reads on mammalian, including human CD40CR. The instant invention encompasses any CD40CR as a target of the instant methods, yet the instant specification does not provide sufficient written description as to the structural features of said CD40CR and the correlation between the chemical structure and the function of the genus of CD40CRs. Applicant appears to rely upon the disclosure of a limited example of a mouse CD40CR.

While Section 7 of the instant specification discloses binding of CD40lg to human T cell lines, there is no isolation nor written description of the human CD40CR.

Furthermore, there is insufficient written description of the genus of CD40CR(s), including as it reads on mammalian as well as human CD40CR.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required.

Further, Skolnick et al. (Trends in Biotech., 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance upon the mouse CD40CR disclosed as filed does not appear to provide sufficient written description of a genus of distinct molecules of "CD40CR(s), encompassed by the claimed invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "CD40CR(s); one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

10. Claims 42, 44, 46, 48, 50, 52, 54-58:

It is apparent that the MR1 antibody / hybridoma is required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

Given the disclosure and the assurance on page 31 of the instant specification, the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to the "hybridoma having ATCC Accession No. HB 11048" have been satisfied.

Applicant is reminded that the following and should amend the specification accordingly.

The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

11. Claims 48 and 54-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 48 and 54-58 are indefinite in the recitation of "5c8" because its characteristics are not known or in the recitation of "monoclonal antibody 5c8 produced by the hybridoma having ATCC No. HB 11048" because the use of "5c8" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "5c8" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct cell lines or hybridomas. Alternatively, the "hybridoma having ATCC No. HB 11048" produces the "MR1 antibody" and not the "5c8 antibody".

B) Claims 54-55 are indefinite in they lack proper antecedent basis for "or fragment thereof" to claims 42-48.
Applicant is invited to amend the recitation of "and fragments thereof" at the end of the claim to recite functional language.

C) Claims 55-56 lacks proper antecedent basis by broadening the independent recitation of an antibody and antibody fragment to an antibody conjugate.

D) The amendments must be supported by the specification so as not to add any new matter.
See MPEP 714.02 and 2163.06

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 43, 45, 47, (48), 49, 51 and 53-58 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document). Lederman et al. teach methods of inhibiting humoral immune responses, including B cell activation and immunoglobulin production by 5c8-specific antibodies (e.g., see Background of the Invention, columns 10-11, and Example 7 on columns 23-27), including antibody fragments, chimeric, humanized and human antibodies as well as antibody conjugates (columns 6-8) (also, see Claims). The 5c8 specificity is the equivalent of the human CD40 ligand or CD40CR, as recited in the instant claims. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to inhibit humoral immune responses, B cell activation and immunoglobulin production by 5c8-specific antibodies.

Given the ambiguity of the recitation of "5c8" in claim 48 as addressed above, Lederman et al. is applied to claim 48. It is noted that the "hybridoma having ATCC No. HB 11048" in claim 48 produces the "MR1 antibody" and not the "5c8 antibody".

15. Claims 42-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816) in view of Armitage et al. (U.S. Patent No. 5,961,974).

Lederman et al. teach methods of inhibiting humoral immune responses, including B cell activation and immunoglobulin production by helper T cell-specific antibodies, including the 5c8-specific antibodies (e.g., see Background of the Invention, columns 10-11, and Example 7 on columns 23-27), including antibody fragments, chimeric, humanized and human antibodies as well as antibody conjugates (columns 6-8) (also, see Claims). The 5c8 specificity is the equivalent of the human CD40 ligand or CD40CR, as recited in the instant claims.

Lederman et al. differs from the claimed methods by not disclosing the protein specifically recognized by the MR1 antibody which binds the mouse CD40 ligand (CD40L).

Armitage et al. teach the mouse and human CD40L on T cells, wherein CD40L is involved in T - B cell interactions, which are associated with B cell proliferation and differentiation resulting in immunoglobulin secretion (See entire document, including Detailed Description of the Invention and Examples 1-13). Armitage et al. Teach the use of antagonists of CD40:CD40L interactions which prevent CD40L binding to CD40 sites on B cells and other target cells, which can be used in therapeutic modalities (see Detailed Description of the Invention) (e.g. columns 10-11, including overlapping paragraph, columns 14-17; column 21)

Given the ability of helper T cell 5C8-/CD40L-specific antibodies, as taught by Lederman et al. OR the ability of various CD40 antagonists, as taught by Armitage et al. to inhibit various immune responses, including T helper cell-mediated immune responses, including humoral responses; one of ordinary skill in the art at the time the invention was made would have been motivated to generate antibody antagonists, including antibody fragments, chimeric, humanized, human antibodies as well as antibody conjugates, as known by the ordinary artisan and taught by Lederman et al. to the mouse and human CD40L taught by Armitage et al. to similarly target T helper cells in order to inhibit humoral responses, B cell proliferation and immunoglobulin production. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claims 42-53, (54) and 55 (and 56-58) are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816)
or over Lederman et al. (U.S. Patent No. 5,993,816) in view of Armitage et al. (U.S. Patent No. 5,961,974) in view of the art known use of antibody conjugates in inhibiting immune responses by the ordinary artisan at the time the invention was made, as evidenced by Ultee et al. (U.S. Patent No. 4,937,183).

Lederman et al. and Lederman et al. in view of Armitage et al. are taught above and differ from the claimed methods by not disclosing all of the well known antibody conjugates recited in claim 55.

A wide variety of antibody conjugates for inhibiting immune responses were well known and practiced by the ordinary artisan at the time the invention was made, including those recited in claim 55, as evidenced by Ultee et al. (See entire document, including Section 5.2, particularly columns 7-8, overlapping paragraph, Sections 5.3, 5.4, 5.5).

Given the well known use of a variety of antibody conjugates employed in therapeutic modalities to inhibit immune responses, it would have been obvious to one of ordinary skill in the art to conjugate either human or mouse CD40L-specific antibodies to inhibit humoral immune responses, including the inhibition of B cell activation and immunoglobulin production, as taught by Lederman et al. or Lederman et al. in view of Armitage et al. as taught above, at the time the invention was made. The various conjugates were well known to provide additional immunosuppressant properties for therapeutic antibodies that target cells of interest at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
January 3, 2003

Appl[redacted]ion No. 09/467317

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☑ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7.

Other: _____

Applicant must provide:

☑ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☑ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☑ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.